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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,763	04/13/2006	Shigehiko Mizutani	47234500500US	3821
55694 7590 12/14/2007 DRINKER BIDDLE & REATH (DC) 1500 K STREET, N.W. SUITE 1100 WASHINGTON, DC 20005-1209			EXAMINER GUSSOW, ANNE	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 12/14/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/575,763

Applicant(s)

MIZUTANI, SHIGEHIKO

Examiner

Anne M. Gussow

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 16 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17 is/are allowed.
- 6) ☒ Claim(s) 11-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Claim 11 has been amended.  
Claim 17 has been added.
2. Claims 11-15 and 17 are under examination.

***Rejections Withdrawn***

3. The rejection of claims 11-15 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment to the claims.
4. The rejection of claims 11-15 under 35 U.S.C. 112, first paragraph, as lacking enablement is withdrawn in view of applicant's amendment to the claims.

***Rejections Maintained***

5. The rejection of claims 11-15 under 35 U.S.C. 102(a) as being anticipated by Suzuki, et al. is maintained.

The response filed October 12, 2007 has been carefully considered but is deemed not to be persuasive. The response states that the Suzuki reference does not disclose all the elements of the claimed method and, as such, does not properly anticipate the claimed invention. In this case, the presently claimed method comprises:  
(a) contacting P-LAP positive carcinoma tissues obtained from carcinoma patients with

an anti-P-LAP antibody, (b) measuring the intensity of the specific antigen-antibody binding between P-LAP present in the carcinoma tissues and anti-P-LAP antibody, and (c) correlating the intensity of the specific antigen-antibody binding with prognosis of carcinoma. Giving the terms of the claim their broadest possible interpretation in light of the specification, to correlate binding with a "prognosis" means that binding is correlated with "a prediction of the probable course and outcome of a disease" or "the likelihood of recovery from a disease." See, e.g., The Free Dictionary, at <http://www.thefreedictionary.com/prognosis> (last accessed May 10, 2007).

In response to this argument, Suzuki, et al. teaches each of steps a, b and c, as claimed in the instant invention. Figure 1 illustrates detection of p-LAP in endometrioid adenocarcinoma tissues by immunohistochemistry (step a) and correlation of the intensity of staining (step b) with the grade of tumor (step c). Suzuki, et al. illustrates in figure 1G that increasing grade of tumor had an increasing amount of p-LAP expression. One of skill in the art would know that the higher grade of tumor is associated with a more advanced stage of disease and thus a lower chance of survival or a worse prognosis. Suzuki, et al. teach an anti-human p-LAP antibody was used in the immunohistochemistry experiments (page 1529, 1<sup>st</sup> column).

Therefore, after a fresh consideration of the claims and the evidence provided, the rejection is maintained.

### ***Conclusion***

6. Claim 17 is in condition for allowance.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

December 11, 2007

/Larry R. Helms/  
Supervisory Patent Examiner